JUN 2 9 2011

510K SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Devices Act of 1990 and 21 CFR 807.92

The assigned 510(k) number is: K110616

Company/Contact person
Lisa Charter
Manager, Regulatory Affairs
Microgenics Corporation
Thermo Fisher Scientific, Clinical Diagnostics Division
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Date Prepared
June 20, 2011

Regulatory Declarations

Common / Usual Name	MAS® Omni•IMMUNE MAS® Omni•IMMUNE PRO
Trade/ Proprietary Name	Thermo Scientific MAS® Omni•IMMUNE Thermo Scientific MAS® Omni•IMMUNE PRO
Classification Regulation	21 CFR 862.1660
Device Class	Class I
Device Regulation Panel	Clinical Chemistry
Product Code	JJY

Intended use
Thermo Scientific MAS® Omni•IMMUNE is intended for use as an assayed control for monitoring assay conditions in many clinical laboratory determinations. Include Omni•IMMUNE with patient serum specimens when assaying for any of the listed constituents. Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument

Thermo Scientific MAS® Omni•IMMUNE PRO is intended for use as an assayed control for monitoring assay conditions in many clinical laboratory determinations. Include Omni•IMMUNE PRO with patient serum specimens when assaying for any of the listed constituents. Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.

Legally marketed device to which equivalency is claimed

Thermo Scientific MAS Omni•IMMUNE Control is substantially equivalent to the previously cleared Bio-Rad Laboratories Lyphochek Immunoassay Plus Control (K981532).

Description of Device

Omni•IMMUNE is a liquid stable control material prepared from human serum. Analyte levels are adjusted with various pure chemicals and preparations from human tissue or body fluids. Preservatives and stabilizers are added to maintain product integrity.

The control is offered in three levels with the following configuration:

MAS® Omni•IMMUNE		
Catalog Number	**Description**	**Size**
OIM-101	Level 1	6 vials of Level 1, 5 mLs per vial
OIM-202	Level 2	6 vials of Level 2, 5 mLs per vial
OIM-303	Level 3	6 vials of Level 3, 5 mLs per vial
OIM-SP	Sample-pack	1 vial of Level 1, 5 mLs per vial 1 vial of Level 2, 5 mLs per vial 1 vial of Level 3, 5 mLs per vial
MAS® Omni•IMMUNE PRO		
Catalog Number	**Description**	**Size**
OPRO-1	Level 1	6 vials of Level 1, 5 mLs per vial
OPRO-2	Level 2	6 vials of Level 2, 5 mLs per vial
OPRO-3	Level 3	6 vials of Level 3, 5 mLs per vial
OPRO-SP	Sample-pack	1 vial of Level 1, 5 mLs per vial 1 vial of Level 2, 5 mLs per vial 1 vial of Level 3, 5 mLs per vial

Comparison of Technological Characteristics

Comparison	Subject Device	Predicate
Device	MAS® Omni•IMMUNE MAS® Omni•IMMUNE PRO	Bio-Rad Lyphochek® Immunoassay Plus Control
510(k) number	K110616	K981532
Intended Use	Thermo Scientific MAS® Omni•IMMUNE is intended for use as an assayed control for monitoring assay conditions in many clinical laboratory determinations. Include Omni•IMMUNE with patient serum specimens when assaying for any of the listed constituents. Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument Thermo Scientific MAS® Omni•IMMUNE PRO is intended for use as an assayed control for monitoring assay conditions in many clinical laboratory determinations. Include Omni•IMMUNE PRO with patient serum specimens when assaying for any of the listed constituents. Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.	Lyphochek Immunoassay Plus Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.
Matrix	Human Serum	Human Serum
Form	Frozen Liquid	Lyophilized
Control Levels	Level 1 Level 2 Level 3	Level 1 Level 2 Level 3
Storage	-20°C	2-8°C
Open Vial Stability	30 days (2-8 °C)	7 days (2-8 °C) except 1. C-Peptide, Folate and PSA (stable for 3 days after reconstitution). 2. ACTH, Calcitonin and Gastrin (Should be assayed immediately after reconstitution).
Shelf Life	36 months	36 months
Analytes by Configuration	17-alpha-OH Progesterone 25-Hydroxy Vit D Acetaminophen ACTH AFP	17-alpha-OH Progesterone 25-Hydroxy Vit D Acetaminophen ACTH AFP

	Aldosterone	Aldosterone
	Amikacin	Amikacin
	Anti-Tg (PRO Version Only)	Anti-Tg
	Anti-TPO (PRO Version Only)	Anti-TPO
	Benzodiazepine	-
	Beta-2-Microglobulin	-
	CA 125	-
	CA 15-3	-
	CA 19-9	-
	ß-hCG	Calcitonin
	Carbamazepine	ß-hCG
	CEA	Carbamazepine
	CK-MB (MMB)	CEA
	Cortisol	-
	C-Peptide	Cortisol
	DHEA-Sulfate	C-Peptide
	Digoxin	DHEA-Sulfate
	Disopyramide	Digoxin
	Estradiol	Disopyramide
	Estriol free	Estradiol
	Ethosuximide	Estriol free
	Ferritin	Ethosuximide
	Folate	Ferritin
	Fructosamine	Folate
	FSH	Fructosamine
	Gastrin	FSH
	Gentamicin	Gastrin
	Growth Hormone	Gentamicin
	hCG	Growth Hormone
	Homocysteine	hCG
	IgE	-
	IGF-1	IgE
	Inhibin A	-
	Insulin	-
	LH	Insulin
	Lidocaine	LH
	Lithium	Lidocaine
	NAPA	Lithium
	PAP	NAPA
	Phenobarbital	-
	Phenytoin	PAP
	Phenytoin, Free	-
	Primidone	Phenobarbital
	Procainamide	Phenytoin
	Procalcitonin	Phenytoin, Free
	Progesterone	Primidone
	Prolactin	Procainamide
	PSA	-
	Free PSA	Progesterone
	PTH, Intact	Prolactin
	Quinidine	PSA
	Salicylate	Free PSA
	SHBG (PRO Version Only)	PTH, Intact
	TBG	Quinidine
	T3	Salicylate
	Free T3	SHBG

	T4 Free T4 Testosterone Theophylline Thyroglobulin Tobramycin Tri-Cyclic Antidepressants TSH T-Uptake Valproic Acid Valproic Acid, Free Vancomycin Vitamin B12	TBG T3 Free T3 T4 Free T4 Testosterone Theophylline Thyroglobulin Tobramycin Tri-Cyclic Antidepressants TSH T-Uptake Valproic Acid Valproic Acid, Free Vancomycin Vitamin B12

Conclusion

As summarized, the Omni•IMMUNE Control is substantially equivalent to the previously cleared Bio-Rad Lyphochek® Immunoassay Plus Control (K981532). Substantial equivalence has been demonstrated through performance testing to verify that the device functions as intended and that design specifications have been satisfied.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

JUN 29 2011

Microgenics Corporation
Thermo Fisher Scientific Clinical Diagnostic Division
c/o Ms. Lisa Charter
Manager, Regulatory Affairs
46360 Fremont Blvd.
Fremont, CA 94538

Re: k110616
Trade Name: Thermo Scientific MAS Omni-Immune, Thermo Scientific MAS Omni-Immune Pro
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality Control Material (assayed and unassayed)
Regulatory Class: Class I, reserved
Product Codes: JJY
Dated: May 19, 2011
Received: May 23, 2011

Dear Ms. Charter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K110616

Device Name: Thermo Scientific MAS® Omni•IMMUNE
Thermo Scientific MAS® Omni•IMMUNE PRO

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Prescription Use __X__ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K110616